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| 09/976,746      | 10/12/2001  | Michael A. McDonald  | 004367.00005        | 2198             |

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/976,746

**Applicant(s)**

MCDONALD ET AL.

**Examiner**

Michael G. Hartley

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14, 15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                      6) ☐ Other: \_\_\_\_\_.

Art Unit: 1616

***Response to Amendment***

The amendment filed 10/22/2003 has been entered.

***Response to Arguments***

Applicant's arguments with respect to claims 1-8, 14, 15 and 17-22 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 7, 8, 14, 15, 17, 18, 19 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger (US 6,416,740).

Unger discloses a contrast agent composition comprising one or more metal particles and one or more microsphere shells wherein the metal particles are integrated within the layers or walls of the microspheres (e.g., are between the inner and outer walls as claimed, as they are within the vesicles walls of the hollow (gas-filled vesicles), see column 10, lines 30-35, column 37, lines 55-57 and column 76, lines 11+. Unger also discloses that the metal particles are metal oxide particles, which are nano- or micro- particles, see column 37, lines 29-39. Also, since the above recited instant claims do specify the size of the particles and state that the particles are selected from the group consisting of gadolinium..., even a metal would be within the scope of a particle, as claimed (e.g., a metal particle or particle of metal, a particle of gadolinium). Note, claim 5 states "no more than about 450 Å" and a particle of metal would be within the lower limit thereof. Unger teaches the use of various metals, including Gd, which would be

Art Unit: 1616

within the scope of a particle (i.e., a particle of metal), see column 35. Unger specifically discloses that the particles may be used for more than one type of imaging modality, by stating that the imaging uses ultrasound, CT and/or MRI, the "and" therein clearly discloses multiple imaging modalities, see column 65, lines 40-39 and column 39. Unger discloses that various vesicles may be used in the compositions, including proteins (i.e., albumins), as the shell material, see columns 5 and 10. The vesicles are used integrate the paramagnetic particles between vesicle walls, which are 10 to 15 nm (10 to 150 Angstroms) in size, which is within the claimed size range, see column 37. The metals include manganese, as well as Gd, see columns 35-37.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 14, 15 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Unger (US 6,416,740) in view of Gordon (US 4,735,796).

Unger discloses a contrast agent composition comprising one or more metal particles which are embedded in between the walls of the vesicles, as set forth above. Unger also teaches that the metal particles are particles of metal oxides (spherical), which are within the size range claimed and teaches that the metal may be gadolinium. Unger fails to specifically disclose that the particles are gadolinium oxide particles. However, the use of gadolinium oxide particles as an effective contrast agent is well known in the art, as shown by Gordon.

Gordon discloses paramagnetic contrast agents comprising metal particles and teaches that gadolinium oxide is known to be useful as a contrast agent and equivalent to other metal oxide particles, see column 6.

Art Unit: 1616

It would have been obvious to one of ordinary skill in the art to Gd as the metal oxide particles disclosed by Unger because Unger teaches that various metal oxide particles may be employed, and specifically recites manganese oxide particles, while teaching Gd is an equivalent metal to manganese (see columns 35-37) and because Gd oxide particles are well known to be equivalent (or preferred) to the metal oxide particles disclosed by Unger, as shown by Gordon. Unger teaches the use of metal oxide particles and gadolinium oxide particles are known to be an effective contrast agent that is equivalent to other metal oxides, as shown by Gordon, as well as Unger. Thus, one of ordinary skill in the art would have been motivated to use Gd oxide particles as the metal oxide disclosed by Unger because of the well established use of Gd in the metal oxide particles disclosed for MRI as taught by Gordon and Unger.

### **Conclusion**

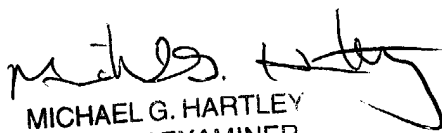
No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER

Michael G. Hartley